

EXHIBIT C

Part 1 of 2

**Lupin's Arguments re
Irreparable Injury and Recall**

December 2, 2011

Sciele Pharma, Inc., et al. v. Lupin Ltd., et al.

C.A. No. 09-037 (D.Del)

Summary of Lupin's Arguments

- ✱ Every one of Shionogi's claimed harms is quantifiable
 - ✱ Loss of sales – for whatever reason – can be calculated and quantified
- ✱ Shionogi's claimed injuries are not supported by any case-specific evidence
 - ✱ Facts show Shionogi gave up on Fortamet® market well before Lupin's launch
- ✱ Shionogi essentially argues that generic launches routinely should be enjoined, although preliminary injunction is an extraordinary remedy
- ✱ The exceptional and unusual relief of recall is unwarranted

Shionogi's Market for Fortamet® Was Declining Long Before Lupin's Launch

- ✱ Shionogi stopped sales and promotion efforts in August 2010

Melloy Decl., ¶ 12, Tab 1

- ✱ According to a Shionogi executive: "in financial terms, Shionogi decided that there would not be an adequate return on investment to justify the expense of active promotion"

Melloy Decl., ¶ 12, Tab 1

- ✱ Shionogi stopped promoting even though it recognized that promotional activities were necessary to slow market decline

2010 Fortamet® Brand Plan, SHIO 019389, 019396, Tab 2

- ✱ Shionogi never captured more than about 1% of the market

2010 Fortamet® Brand Plan, SHIO 019389, Tab 2

- ✱ Unit sales were declining for several years; Shionogi's response was to raise prices

Fortamet® IMS Data, Tab 3; Hoffman Decl., ¶ 25 and Ex. A, Tabs 4 and 5; LUP 0066407-413, 0066418, Tab 21

Even Before Lupin's Launch, Shionogi Expected the Market to Continue to Decline

- ✱ Before Lupin's launch, Shionogi forecast that its market would shrink approximately 25% from FY 2011 to FY 2012
- ✱ Forecast net sales without generic entry was \$51.2 million in FY 2011 (annualized) and \$38.5 million in FY 2012

SHIO 019556, Tab 9

SHIO 019556, Tab 9

Shionogi Essentially Abandoned the 500 mg Fortamet® Market One Year Before Lupin's Launch

- * Sharply decreasing sales of 500 mg; orders not being filled for several months

Fortamet® IMS Data, Tab 3; Hoffman Decl., ¶ 14, Tab 4

- * “[B]ecause of a manufacturing issue that Watson detected in November 2010”

Melloy Decl., ¶ 15, Tab 1

- * “[M]anufacturing issue” not expected to be resolved until the week of October 24, 2011 (almost one year later)

Melloy Decl., ¶ 15, Tab 1

- * Absence of 500 mg product caused further erosion to Fortamet® franchise irrespective of Lupin launch

Hoffman Decl., ¶ 15, Tab 4

- * Shionogi decided to emphasize the 1,000 mg dosage in 2010 marketing

2010 Fortamet® Brand Plan, SHIO 019398, Tab 2

Fortamet® Already Competes In a ‘Highly Saturated’ ‘Genericized Market’

- ✱ According to Shionogi’s Fortamet® Business Plan 2008:
 - ✱ Market is “highly saturated with generic equivalents”
 - ✱ Fortamet® “currently competes against 14 generic metformin extended release formulations and 22 generic metformin immediate release formulations in addition to a new branded extended release formulation – Glumetza”
 - ✱ Fortamet® also competes against five other branded metformin combination products
- ✱ Watson’s authorized generic is likely to join this crowded field

SHIO 019367, Tab 6

Agreement to License, SHIO 019467-468, Tab 7

Authorized Generic Fortamet®

- * License Agreement permits Watson to launch an authorized generic

SHIO 019467-468, Tab 7

- * Even if Lupin is no longer on the market

- * Watson will pay a royalty to Shionogi

SHIO 019511, Tab 7

- * Arms-length negotiation is significant proof that damages are quantifiable

- * Failure to provide for brand control or cessation of marketing if generic is removed from the market is significant proof that money damages will suffice

- * Shionogi paid 8% royalty to Watson before the Lupin launch

SHIO 019457, Tab 7

Delay Further Illustrates No Irreparable Injury

Warnings of launch

- ✱ *Wall Street Journal* two days before launch

Tab 10

- ✱ *Wall Street Journal* in June

Tab 11

- ✱ Lupin CEO conversation with Shionogi CEO

Gupta Decl., ¶ 9, Tab 8

- ✱ Settlement negotiations

- ✱ Shionogi requested notice letters in June, not later

Tabs 12 and 13

- ✱ Termination of settlement agreement

Gupta Decl., ¶ 8, Tab 8; Hoffman Decl., ¶ 36, Tab 4;
Settlement and Release Agreement, Tab 14

- ✱ Market information

Shionogi's Slow Reaction Shows Lack of Irreparable Harm

- ✱ Despite information about launch on Friday, there was no contact until late Sunday morning and then only asked for “confirmation” the next day – three days after launch
- ✱ Once confirmed, Shionogi did not seek a TRO or prompt standstill, but requested a lengthy briefing schedule
- ✱ No standstill for almost three weeks – and premarketing was allowed to continue

E-mail correspondence, Tab 15

Shionogi Had Given Up on Fortamet® Market Before Lupin Launched

- * Sales were never strong to begin with; 1% of the market at best
2010 Fortamet® Brand Plan, SHIO 019389, Tab 2
- * Sales continued to decline; Shionogi projected 25% decline from FY 2011 to FY 2012 (even without generic competition)
SHIO 019556, Tab 9
- * Shionogi's short-term strategy: milk the market for what it can get now
 - * Raised prices despite falling volume
 - * 500 mg issue left unresolved for a year
 - * Stopped promoting one year ago
 - * Apparently no long-term plans for Fortamet® market

Indications That Watson Will Launch Authorized Generic

- ✱ Standstill does not bar premarketing
- ✱ Market information from customers – activities of Watson's sales representatives
- ✱ Watson e-mails showing preparations

Hoffman Decl., ¶ 5, Tab 4

SHIO 019419-421, Tab 16; AND 184710-711, Tab 17

Shionogi's Claimed Harms Are Either Quantifiable or Completely Speculative

Quantifiable

- ✱ Lost sales are quantifiable, whether to Lupin, Mylan, or Watson
- ✱ Loss of formulary position is just another explanation for lost sales

Speculative

- ✱ Loss of goodwill
- ✱ Lost jobs
- ✱ Shutdown of Shionogi U.S.

Shionogi's Claimed Harms Are Just Lost Sales Dressed Up in Different Clothing

Merely reasons for why sales will be lost

- ✱ **Formulary position**

Gleason/Hofmann Decl., ¶ 55-56 and Ex. 23, Tabs 24 and 25; 2008 Business Plan, SHIO 019367, Tab 6

- ✱ Almost all formularies have Fortamet® on Tier 3 now
- ✱ Glucophage experience – unlikely to be unlisted even with generic option
- ✱ Lower prices
- ✱ Authorized generic or other generic competition
- ✱ Loss of goodwill leading patients to other metformin products

Dollar Value of Lost Sales Is Easily Calculated

- ✱ Mature market – much historic information
- ✱ IMS data will show pre- and post-launch sales
- ✱ Shionogi's own projections
- ✱ Decrease in orders is quantifiable
- ✱ The entire Fortamet® franchise is forecast at \$38.5 million for FY 2012 and has been in rapid decline
- ✱ Undisputed that Lupin has the ability to pay damages

Gupta Decl., ¶ 5, Tab 5; Lupin Annual Report 2011, Tab 18

Shionogi's Claimed 'Complications' and 'Uncertainties' Only Go to the Reasons for Lost Sales

- ✱ Other generics
- ✱ Mylan on market in one year
- ✱ Authorized generic
- ✱ Most “uncertainties” will be known by time of trial
- ✱ Maximum damages is the total size of the market, which is known – so it is quantifiable
- ✱ These are questions of allocation, not computation

No Evidence, Just Speculation

- * Claims of non-economic injury are not supported by any evidence or document
 - * Problems with Japanese parent
 - * Customer reaction to prices and loss of goodwill
 - * Loss of jobs
 - * Inability to market new products
- * Shionogi has shown ability to react to generic competition
 - * History
 - * Projections

E.g., SHIO 019556, Tab 9; SHIO 019391, Tab 2

Supposed Problems With Japanese Parent And Shutdown of Shionogi U.S.

- * Nothing other than conclusory statement by Melloy
- * Reason for acquisition remains – U.S. outlet
Shionogi Annual Report 2011, Tab 19
- * Still \$250 million in net sales from Shionogi U.S. without Fortamet®
SHIO 019411, Tab 22
- * Shionogi 2011 Annual Report indicates sticking with U.S. subsidiary despite its problems; indicates any problems are structural, not due to Lupin launch
Shionogi Annual Report 2011, Tab 19
- * October 28, 2011 press release about revised forecasts does not mention generic Fortamet® competition
LUP 0066407-0066410, Tab 21

Customer Reaction to Prices and Loss of Goodwill

- ✱ No evidence regarding Shionogi's concern that higher prices will result in loss of goodwill
- ✱ Shionogi has raised prices in the past without generic competition
Hoffman Decl., Ex. A, Tab 5
- ✱ Shionogi raised prices since launch
LUP 0066407-413, 0066418, Tab 20
- ✱ Concern not reflected in business reports or non-litigation documents
- ✱ Facts suggest lack of price sensitivity among customers
 - ✱ Customer base held at about 3,000 doctors despite price increase
Melloy Decl., ¶ 10, Tab 1
- ✱ Existing metformin generic competition